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10/069,691	06/03/2002	Stephen Gill	PA-9947	3741

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101 CARNEGIE CENTER
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EXAMINER

HARTLEY, MICHAEL G

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1618

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/069,691
Filing Date: June 03, 2002
Appellant(s): GILL ET AL.

Craig M. Bohlken
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/23/2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. The statement indicates that there are no related appeals; however, there does appear to be a related appeal. An appeal brief in serial number 10/069,690 has been filed on 7/8/2005 and this application is drawn to similar subject matter.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because, first there is no explanation as to why the separately grouped claims do not stand and fall together. Second, the issue is whether or not it would have been obvious to one of ordinary skill in the art to use silica-coated vials for radiopharmaceuticals that include a metal complex. This would hold true for kit claims as well, as it is well known to include such radiopharmaceuticals in a kit. Also, the kit as claimed does not incorporate any further components. As far as claim 10 goes, an organic ligand which forms a coordination complex is always employed in a metal complex, as the term "complex" is a term of art which defines coordination between an organic ligand and a metal. Further, claim 11 should stand together as a bacteriostat is commonly employed in radiopharmaceuticals to avoid contamination, as set forth in the cited art.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (US 5,961,952) in view of any one of JP 11099192 or Schott Gaswerke (DE 29609958) or Walther (US 6,200,658).

Crane discloses a radiopharmaceutical comprising a solution of a metal complex, i.e., an organic ligand (t-butyl isonitrile) complexed with Tc-99m, see abstract. Crane discloses that the radiopharmaceutical compositions are in kit forms containing various components that may be lyophilized and are contained in vials, see column 6. The compositions contain a bacteriostat, such as, a paraben, see column 7, lines 42-46.

Crane fails to disclose that the vials are silica-coated on the inside.

However it is known in the art that vials that are silica-coated on the inside are useful for pharmaceuticals, as well as, radiopharmaceuticals, as shown by JP 11099192 or Schott Gaswerke (DE 29609958) and/or Walther (US 6,200,658).

JP '192 discloses that glass containers with a silica-coated inner surface provides vials having the advantage of accurate measuring of the radiopharmaceutical, see abstract. JP '192 discloses a composition comprising a stabilizer suitable for a metal complex (e.g. chloride) in a container that has a silica coating on the inner surface.

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the compositions disclosed by Crane (i.e., Tc-99m-ligand complex radiopharmaceutical diagnostic agent) by using vials having a silica-coated inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents and radiopharmaceuticals, as taught by JP' 192, DE '958 and Wather, as stated above. One of ordinary skill in the art would have been motivated to use such improved silica-coated vials for the pharmaceutical compositions disclosed by Crane to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Wather (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

(11) Response to Argument

Appellant's arguments filed 6/23/2005 have been fully considered but they are not persuasive.

Appellant states that the examiner refers to silicon coatings at least 8 times and thus, this repeated use of the term "silicon" cannot be explained away by a typographical error. Appellant goes on to state the difference between the terms "silica" and "silicon".

It is noted that the rejection of the claims in the first office action never stated the term, "silicon" but only stated "silica" as this is what is taught by the prior art. The use of the term silicon only was recited in the arguments in the final rejection and was used as shorthand to "oxides of silicon." Clearly, the art discloses oxides of silicon (i.e., silica) as claimed. The relevance of this argument is not

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seen. The original rejection stated silica. In the arguments, the term silicon was used, but clearly the rejection was not changed. Further, the term silicon was meant as silicon-containing, e.g., silicon dioxide or silica. It is unclear how this slight use in terminology changes the merits of the rejection of record. It is further noted that silicon occurs in nature as silicon dioxide or silica. This argument appears to be based on a technicality of typographical error, but not on the merits. It is clear from the original rejection that the term silica was used and that silica is taught by the prior art and that the arguments, which recited silicon, did not change the original rejection.

Appellant asserts that since Crane does not disclose the use of any coating on the vials, Crane fails to provide motivation for improving the vial, let alone coating the inner surface.

This is not found persuasive as obviousness and the motivation to make a change is determined by taking the art as a whole. The primary reference of Crane need not state that their invention needs improvement to be used as a primary reference and to be modified. It is only required that the art as a whole provide the motivation. The motivation comes from the secondary references, which teach that coating the inner surface of vials for various pharmaceuticals, including radiopharmaceuticals, provides various advantages.

Appellant asserts that while JP '192 teaches preventing absorption of radiopharmaceutical products such as thallium chloride, there is no description of using metal complexes as radiopharmaceuticals.

This is not found persuasive because the use of metal complexes as radiopharmaceuticals is very well known in the art, as shown by Crane. It is not clear why this advantage of preventing absorption of the radiopharmaceutical would not hold true for metal complexes as well. No arguments on this point have been presented. One skilled in the art would expect similar advantages from various radiopharmaceuticals, as JP '192 does not teach or suggest the criticality of the radiopharmaceutical to gain the advantage. Further, JP '192 teaches that coating the inner surface of the vials with silica provides the advantage of providing accurate measuring of the radiopharmaceutical. This advantage would be expected with any radiopharmaceutical and the relevance of whether or not the radiopharmaceutical is a metal complex or not is not seen, as this would not appear to change the

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measurement advantage in any way. Obviousness does not require absolute predictability. Also, the art as a whole, as shown by the various secondary references teaches that silica-coated vials provide various advantages for various pharmaceutical agents.

Appellant also asserts that Schott Glaswerke fails to describe the use of radiopharmaceutical metal complexes.

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract. Clearly, radiopharmaceuticals are part of diagnostic agents and pharmaceutical agents. DE '958 does not state the criticality of the pharmaceutical or diagnostic agent, but rather that the advantage may be gained from a broad range of pharmaceutical agents. Clearly, one skilled in the art would believe this advantage to hold true for various pharmaceutical or diagnostic agents and that radiopharmaceutical metal complexes, which are well known, would within this broad group of agents.

Appellant asserts that there is no teaching in Crane of leaching problems and this is the benefit set forth in DE '958.

The primary reference does not need to state a specific problem in the reference for an improvement in the art to be obvious. The leaching problem is taught in the art, by DE '958, that various pharmaceuticals and diagnostic agents suffer from leaching and that problem can be prevented by using silica-coated vials. Clearly, one skilled in the art would see that the benefit would hold true for various pharmaceuticals and diagnostic agents, as taught by DE '958, such as, the pharmaceutical/diagnostic agent disclosed by Crane.

Appellant asserts that Walther fails to refer to radiopharmaceutical metal complexes and thus there would be no motivation to combine with Crane.

Walther teaches the advantage of silica-coated vials with pharmaceuticals, with the advantage being avoiding the disadvantages of dealkylizing process of glass containers. One of ordinary skill in the art would see that this advantage is only critical to the use of glass containers and not the pharmaceutical employed. Pharmaceuticals are commonly contained in glass vials and this teaching would be expected

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to hold true for the use of any pharmaceutical in glass vials or containers. None of secondary references teach the criticality of the pharmaceutical agent, but all suggest by the broad recitations of the agents in the vials, that the agent is not critical and that the advantages would hold true for various pharmaceuticals.

Applicant asserts that the invention of Crane has many features and it unclear why one would choose to improve the vials -of all things- in the invention set forth by Crane.

Obviousness is determined by the art as a whole. Having many features is not a valid argument to obviate a clear teaching of an improvement on one aspect that is recognized in the art.

Appellant asserts that there is no motivation provided by the examiner to address why one of ordinary skill in the art would choose the criteria of vials to improve Crane by the use of silica-coated vials.

To address this argument, it is admitted that Crane is relied upon to show a general teaching that radiopharmaceuticals comprising metal complexes (diagnostic agents) contained in vials and kits are well known. However, the art as a whole does teach various advantages of providing various pharmaceutical agents, including radiopharmaceuticals, in silica-coated vials. There is nothing in the secondary references that would suggest that these advantages could not be gained with various pharmaceuticals, but quite the contrary is taught. Also, the secondary references do not provide any teaching away of "significantly more expense" as asserted by appellant.

Appellant asserts that Crane teaches that solubilization aids are a preferred embodiment to overcome absorption problems and thus would not be motivated to look to solve this same problem by the disclosure of this benefit as taught by JP '192.

This is not found persuasive. Rather this is motivation to combine, as both Crane and JP '192 realized the same problem that needed to be solved, i.e., absorption problems. Just because Crane realizes this problem and finds a means to address this problem in no way means that this would be the end of this issue. Clearly, one skilled in the art would be motivated to consider all the means available to circumvent a problem known in the art. Since Crane and JP '192 both address the same problem, and are in the same field of endeavor, one skilled in the art would have been motivated to combine these two references. The art as a whole clearly teaches advantages of using silica coating vials for vials in the

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same field of endeavor as Crane, as well as, particularly pertinent to the problem being solved, as Crane teaches that absorption is a problem and the cited prior art teaches that absorption of radiopharmaceuticals may be solved using silica-coated vials.

Appellant asserts that the combination would teach away from the present invention by a divergent path of improvements.

This is not seen. The secondary references clearly teach various advantages of using silica-coated vials and that the type of pharmaceutical agent or radiopharmaceutical is not critical to obtaining such advantages. This is not seen as a teaching away. There is nothing in the art to show that one of ordinary skill would have been led away from the use of silica-coated vials. The art does not recognize that solubilization aids are better than silica-coated vials for solving absorption problems. Also, this argument ignores the other advantages taught in the art, e.g., JP '192 teaches that glass containers with a silica-coated inner surface provides vials having the advantage of accurate measuring of the radiopharmaceutical, and Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers. It is unclear how the combination provides any teaching away.

Appellant argues that claims 1, 6, 10 and 11 are separately patentable.

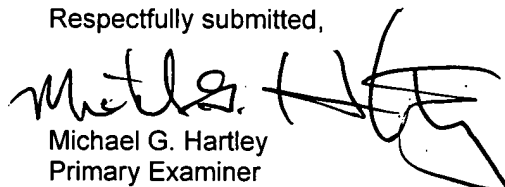
This argument is not seen as the arguments provided therefore are the same as for all the claims, e.g., that the secondary references do not teach metal complexes. This does not address how the other claims are separately patentable, as the same arguments are rehashed. The sole argument is whether or not it would have been obvious to one of ordinary skill in the art to use silica-coated vials for the radiopharmaceuticals disclosed by Crane. If this is true, then all the claims should be rejected, as Crane discloses kits, organic ligands and the use of bacteriostats, but only lacks the use of silica-coated vials. The secondary references provide a teaching in the art, as a whole, that silica-coated vials provide various advantages for various pharmaceuticals agents, which would be expected to hold true for those disclosed by Crane, as clearly, avoiding leaching of radiopharmaceuticals, providing accurate measuring

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of a radiopharmaceutical and minimizing the amount of ions that are leached out of the glass vials, would be advantages desired by the skilled artisan for the radiopharmaceuticals of Crane.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


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Primary Examiner
Art Unit 1618

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November 18, 2005

Conferees
Thurman Page, Supervisory Patent Examiner
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